PatientCentric Care.AI

Building the Safety OS for Healthcare Robotics

Enabling the 'Humanoid 100' to unlock the high-value Healthcare market segment with regulatory-grade compliance infrastructure

$5 Trillion
Total Humanoid Market by 2050

$1 Trillion is Healthcare

The Problem

ATicking Liability Time Bomb waiting for Patients & Manufacturers

Patient Safety Risk

Humanoids in healthcare lacks afety standards and real-world validation

Catastrophic Manufacturer Liability

OEMs face existential legal exposure without regulatory compliance frameworks

Regulation Gap

e.g. Unitree R1 @$5,900
soon in Homes

Technology is advancing faster than regulatory frameworks can keep pace

The Market Catalyst: Morgan Stanley "Humanoid 100"

A global list of 100 public companies identified by Morgan Stanley as the key players shaping the multi-trillion dollar humanoid robot value chain

The BRAIN

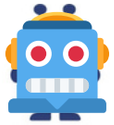
Semiconductors & Software

Companies providing the chips (e.g., NVIDIA), AI models, and software that enable perception, learning, and decision-making.

The BODY

Industrial Components

Companies that manufacture the physical hardware: actuators, sensors, motors, gears, and batteries.



The INTEGRATORS

Full Humanoid Developers

The companies assembling and deploying the complete humanoid robots (e.g., Tesla, Boston Dynamics, Unitree).

Why It Matters for HumanoidHealthcare.AI

This framework validates our entire business model. The ecosystem is fragmented, and no single company does it all.

- It identifies our target customers: **The Integrators** who need a fast, compliant path to the lucrative healthcare market.

Why Now?

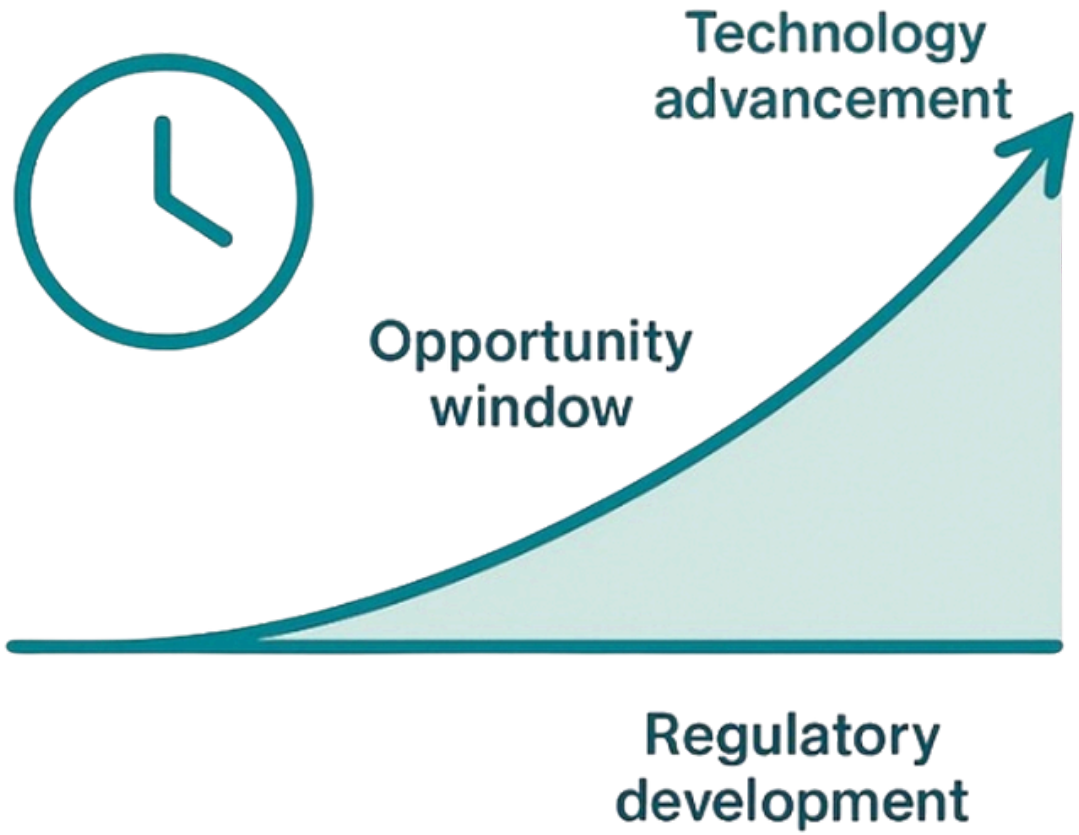
Technology is here. Regulation hasn't caught up.

1.6B people

aged 65+ by 2050

- Aging populations & caregiver shortages
- Explosion of humanoid R&D & falling prices
- **SaMD** Software as a Medical Device

Regulated in US by FDA, and
in EU under **MDR** Medical Device Regulations



Market Opportunity: The Long-Term Vision

Morgan Stanley projects Humanoid Robotics to reach $5 trillion by 2050 (industrial, customer service, home + other)

KEY TAKEAWAYS

$5 Trillion

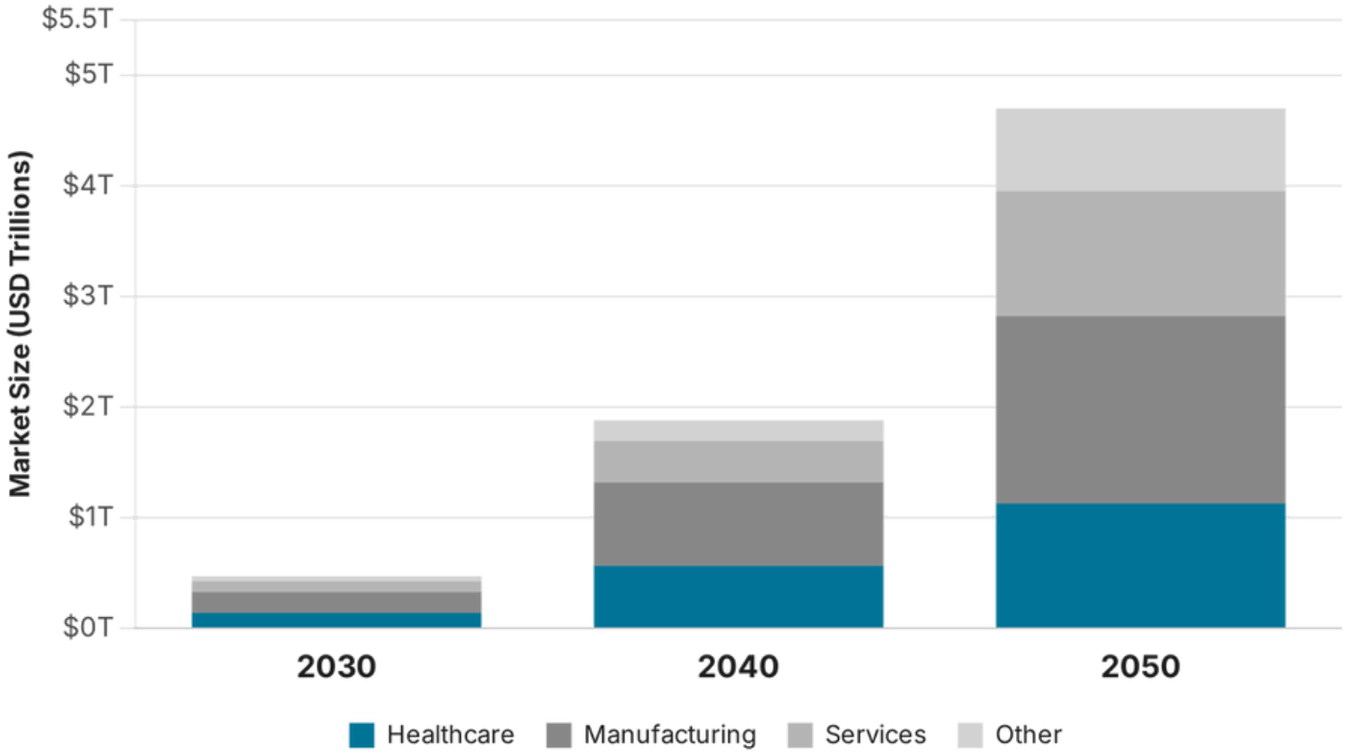
Total humanoid robot market by 2050 across all sectors

$1 Trillion+

Healthcare segment- the high-value segment requiring safety SaMD certification

Late 2030s

Inflection point when regulatory frameworks matureandmassadoption begins



Sources:
Morgan Stanley Research, "The Humanoid Robot Market Could Reach $5 Trillion by 2050" (April 29, 2025);
Morgan Stanley Research, "The Humanoid 100: Mapping the Humanoid Robot Value Chain" (February 6, 2025)

De-Risking Execeution. HMS Collaboration

Harvard Medical School Partnership - immediate placement offered December 2025 for strategic validation

Why this matters

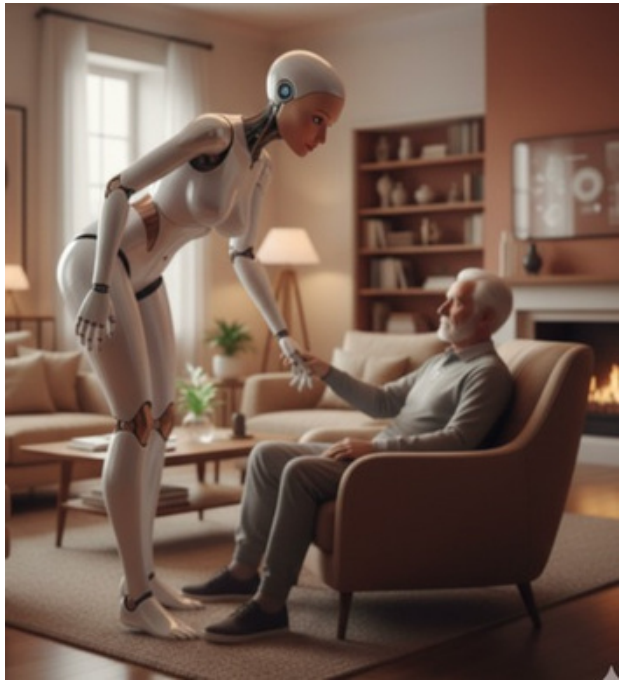
- Academic Credibility: Top-tier medical institution validates our regulatory approach
- Commercial Focus: HMS selected over Johns Hopkins for their emphasis on market readiness
- De-Risked Execution: Partnership accelerates FDA pathway and clinical validation
- Talent Pipeline: Access to HMS network for clinical advisors and pilot sites

Partnership Scope

- Regulatory strategy refinement for FDA SaMD pathway
- Clinical validation protocols for humanoid healthcare applications
- EHR integration best practices
- Access to HMS healthcare innovation network

The $1T+ Healthcare Prize

Healthcare emerges as the highest-value segment requiring safety certification



$1T+

Healthcare Robotics Market by 2050

1 High-Value Healthcare Segment

Healthcare represents a **high-value segment** of the $5T humanoid market, requiring regulatory compliance and safety certification.

2 Mid-late 2030s Inflection Point

Regulatory frameworks mature and mass adoption begins when **certification becomes mandatory** for healthcare deployment.

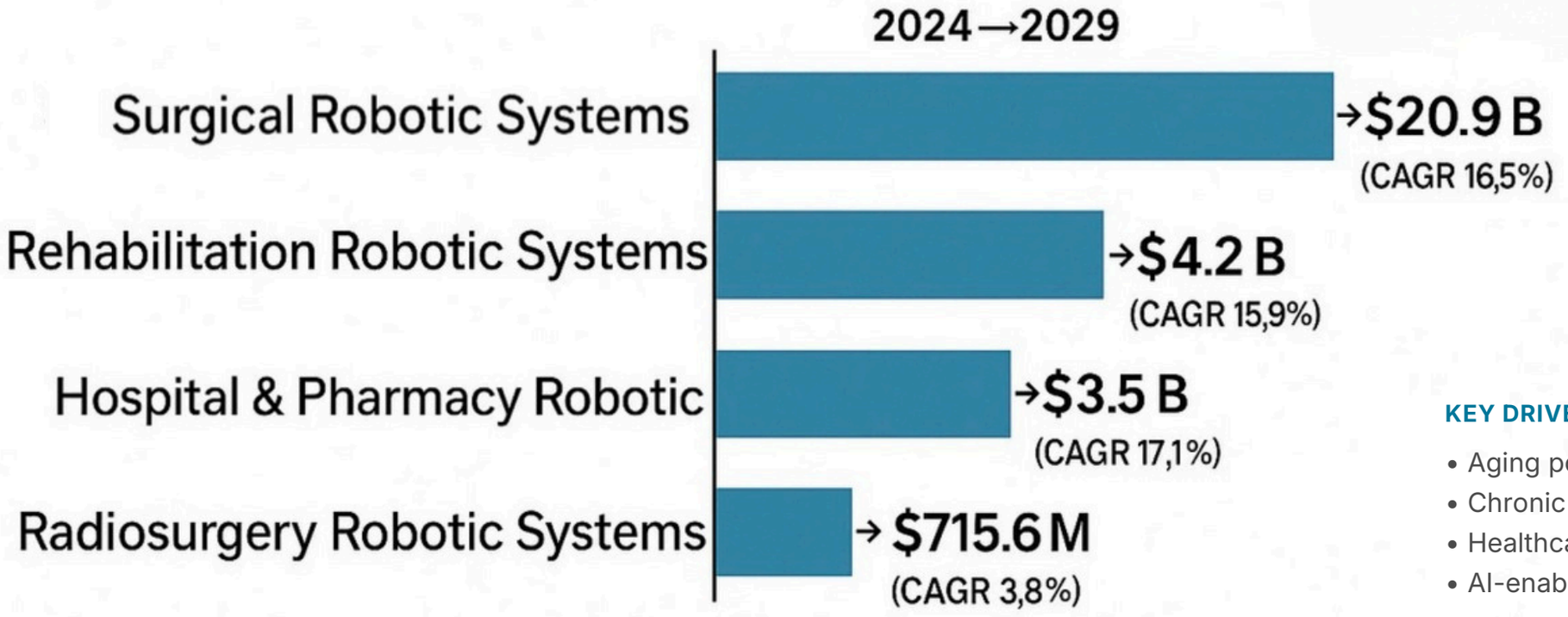
3 Our Core Competency

Regulatory compliance is not a barrier - it's our **competitive moat** and the key to unlocking this trillion-dollar opportunity.

Broader Economic Impact:
The physical embodiment of AI touches a $60 Trillion TAM (total addressable market) across global GDP, representing the full, knock-on economic impact of humanoid robotics across all sectors.

Reality: $33.8B Medical Robots Market by 2029

Our vision of Robot Caregivers in the Home falls within the Rehabilitation Robots segment



KEY DRIVERS

- Aging population
- Chronic disease prevalence
- Healthcare workforce shortages
- AI-enabled robotics advancement

Source: MarketsandMarkets, March 2025

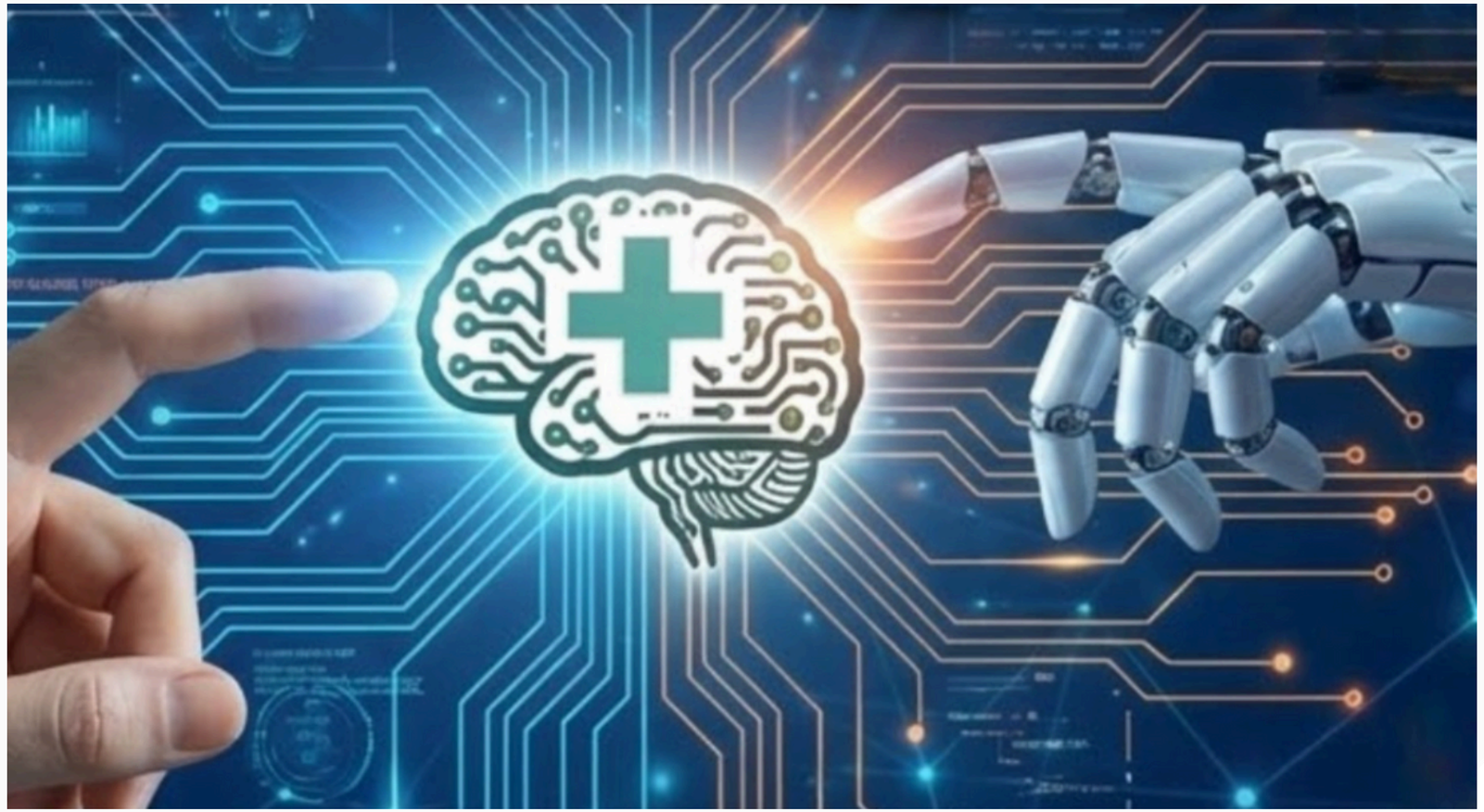
Our Solution: The SaMD Safety OS

Software-as-a-Medical-Device ‘Brain’ Plug-in:

PROTECT PATIENTS

SHIELD OEMs

INDUSTRY STANDARD



OEM = Original Equipment Manufacturer

How It Works: The Modular Architecture

A modular SaMD layer that integrates with any humanoid platform

03

Healthcare Applications

Patient monitoring, elder care assistance, rehabilitation support, and clinical workflows that leverage the certified safety layer below. Foundational HITL - Human (Doctor) in the Loop

Examples: Medication reminders, fall detection, physical & emotional therapy guidance, vital signs monitoring

02

CORE

Our SaMD Safety OS

Modular safety and compliancelayer with real-time monitoring, risk mitigation, and regulatory-grade logging. This is the missing piece that enables healthcare deployment.

FDA SaMD Class II certified • EU MDR compliant • Real-time safety monitoring • Incident response protocols

01

OEM Hardware Platform

Any humanoid robot from the"Humanoid 100" ecosystem. Our hardware-agnostic architecture integrates with any platform via standardized APIs.

Examples: Unitree, Boston Dynamics, Unitree, emerging players from the Morgan Stanley Humanoid 100

Technical Features & Integration

1

Hardware-Agnostic Integration

Works with any humanoid platform via standardized APIs and middleware. Proven integration with an existing Rehabilitation Robot demonstrates compatibility across diverse hardware architectures.

2

Real-TimeSafety Monitoring

Continuous risk assessment and intervention protocols validated through academic partnerships with key Universities. Active monitoring ensures patient safety at every interaction point.

3

Regulatory-Grade Logging

Full audit trails and data capture designed to meet FDA SaMD Class II and EU MDR requirements. Every action, decision, and intervention is logged for regulatory compliance and post-market surveillance.

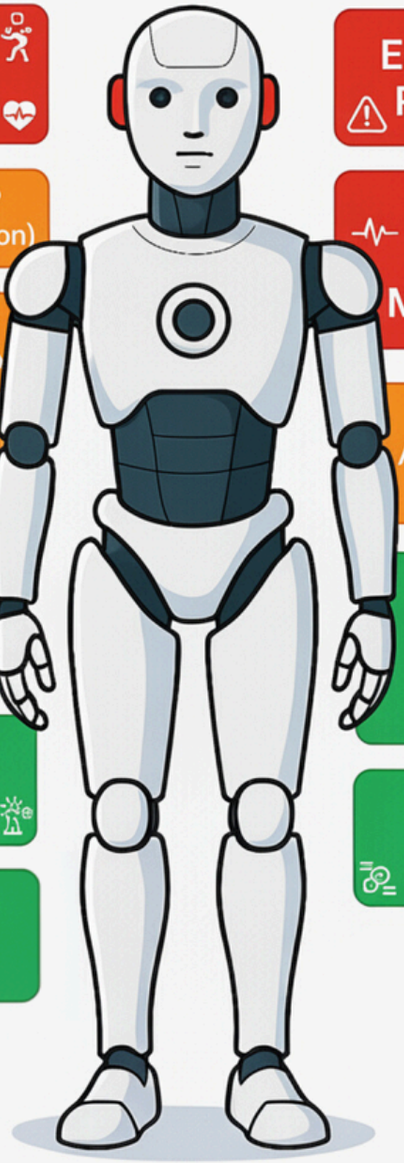
4

Modular Architecture

OEMs can license the complete safety stack or select specific modules based on their deployment needs. Flexible integration allows compliant customisation. Important to follow *TOGAF* AI Enterprise Architecture & for Sensor / EHR data using *HL7 FHIR.*

Humanoid Healthcare SaMD Features

- Patient Lifting & Mobility (Automance)
- Teleprsence (HCP Remote Examination)
- Education & Health Remote Consultatio
- Communication & Social Interactic
- ADL Support (Non-Lifting)
- Physical Assistance
- Environmental Monitoring



- Emergency Protocols
- Critical Patient Monitoring
- User Authentication & Access Control
- Sensor Data Collection & / EHR Integration
- Personalzed Reminders & Scheduling

Software as a Medical (SaMD)

Risk Levels Red = High, Orange = Medium, Green = Low

Regulation is not a barrier. It's our moat.

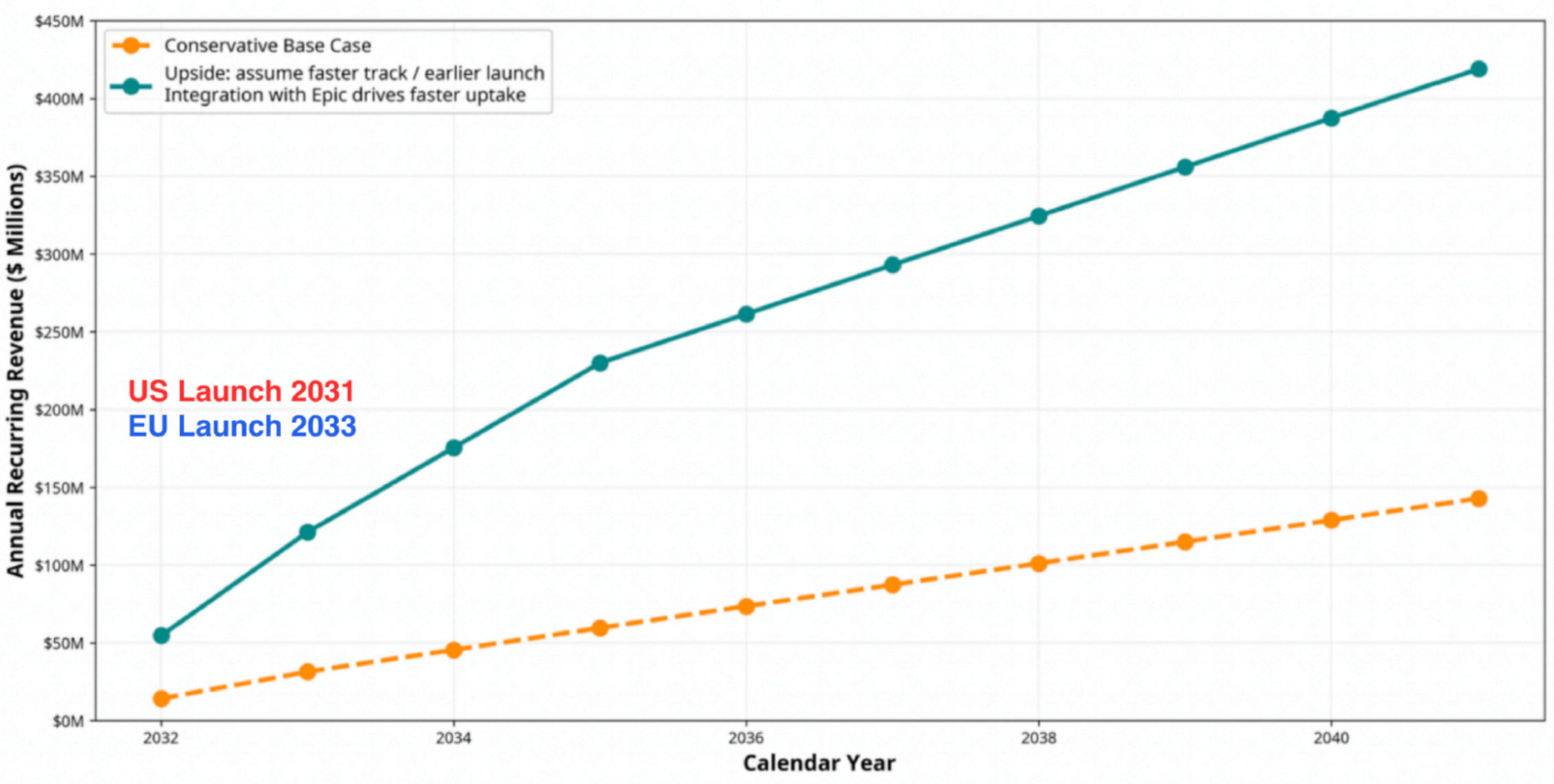
⚠ Competitors avoid regulation → exposed

✓

We turn compliance into defensibility

Full Regulatory Plan at ***HumanoidHealthcare.AI***

Financial Projections: Two Paths to Market Leadership



Our conservative base case delivers strong, venture-scale returns. Our strategic catalysts (regulatory fast-tracking, US market advantage) are designed to unlock the accelerated upside case, creating a generational investment opportunity.

The Investment Thesis: A Generational Financial Return

NET PRESENT VALUE (NPV)

$279M

Demonstrates strong profitability, discounted at 15%

RETURN ON INVESTMENT (ROI)

x 49

4,900% return on total invested capital over the 20-year horizon

PAYBACK PERIOD

Year 4 (2035)

Capital-efficient model achieves payback just as competitors enter

TOTAL NET PROFIT (20-YEAR)

$3.7B

Highlights the long-term potential for market dominance

Financial metrics are calculated based on our 20-year Accelerated Upside Case model.

Our Core Financial Assumptions

Category	Assumption / Rationale
Launch Timeline	US Launch: 2031 (Year 1); EU Launch: 2033 (Year 3)
Unit Price	$15 K per SaMD unit annual recurring license (Tiered pricing via Insurance)
Cost of Revenue (COGS)	5% of Total Revenue (high-margin SaaS model)
Operating Expense (OpEx)	$20M fixed annual cost + 10% of variable revenue
Discount Rate (WACC)	15% (reflecting high-risk, high-growth technology)
Competition	Arrives Year 5 (2035), leading to slower growth post-Year 10
Initial Investment	$6M for pre-launch R&D, pilots, and regulatory prep

> Our model is built on standard, defensible assumptions for a high-margin SaaS business entering a regulated market. The extraordinary returns are driven by the sheer scale of the market opportunity and our unique regulatory moat. $15 K price per SaMD installation, should be compared to >$100 K for a live in Human nurse (& Hospitalisations avoidance)

Go-to-Market Strategy: Phased Plan for Leadership

01 2025 - 2026

Foundation: Pilot & Rapid Validation

- Initial Pilots in Geriatric Care Home US, UK - a controlled environment
- After initial tests, expand to Chronic Cancer Patients rehabilitating at home
- Engage with Regulators Early. Lobby for fast-track. Celebrity Advocates

02 2027 - 2028

Real-World Evidence & Submit SaMD Dossier

- First OEM partnerships from "Humanoid100" ecosystem
- Real-world evidence generation from deployed fleet
- Achieve dual-track SaMD / EU MDR Dossier Submission, with priority functions

03 2029 - 2032

SaMD / MDR Review: Launch US 2031

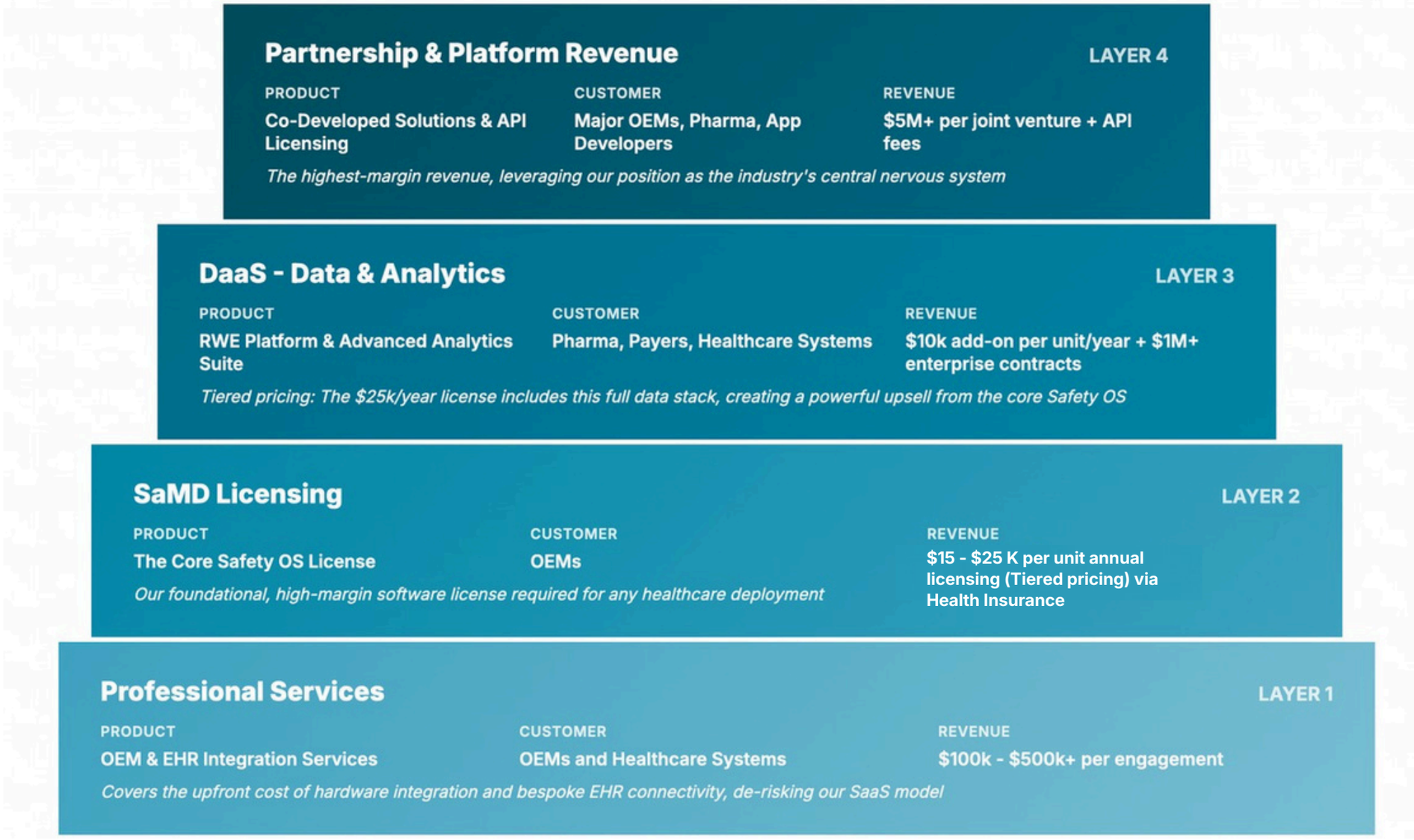
- Build up Marketing machine for launch and make Patients aware
- Secure first US Launch customers patient with OEM partnership
- Build the 3rd Party App Store and prepare all licensing agreements
- Expand the Scaling team for Educations, training & change management
- Connect EHR data via Epic in US, and Robot Sensors with Consent, I&AM

04 2033 - 2040

Launch EU & Scale via The "App Store"Model

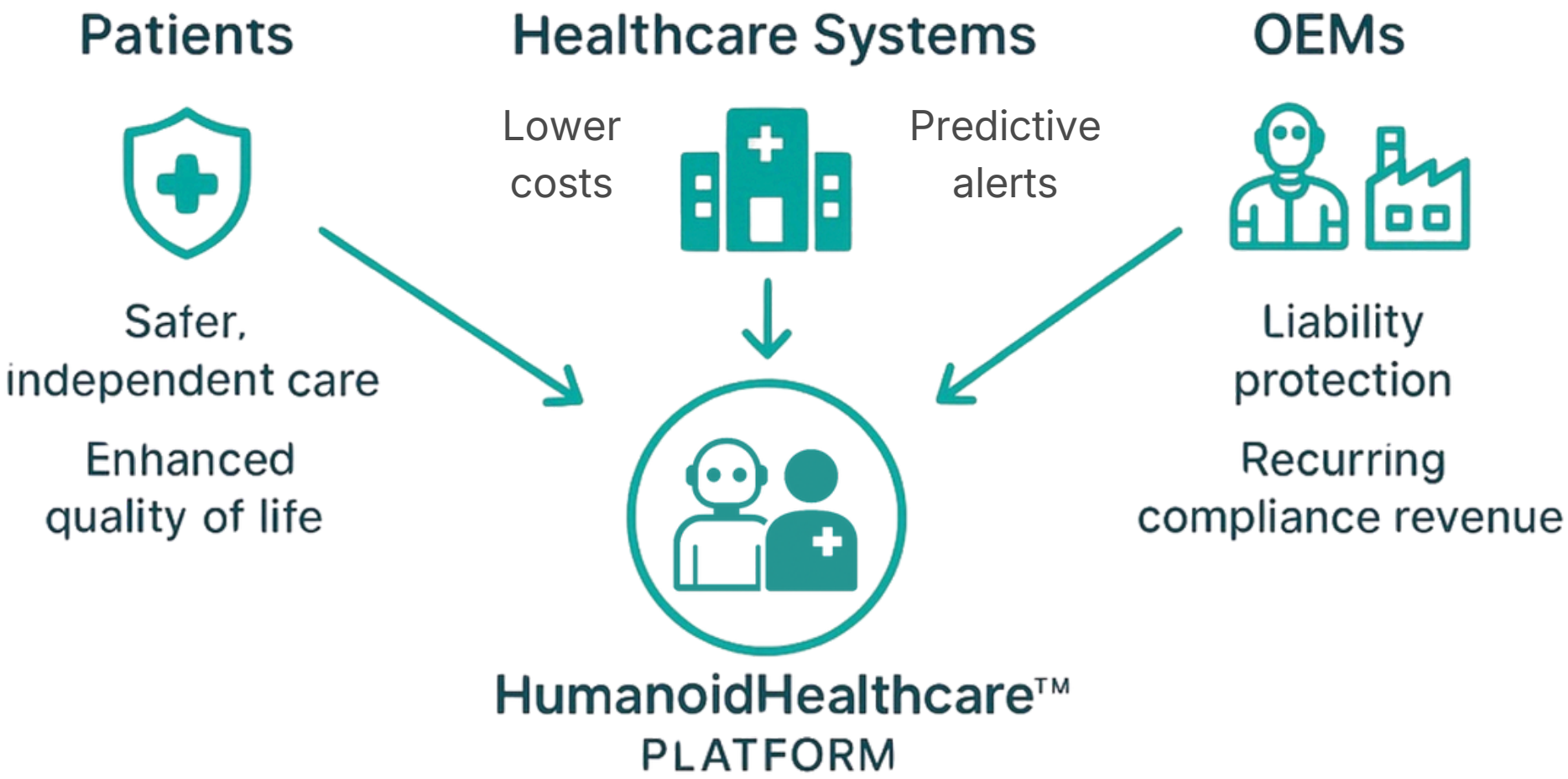
- License our SaMD platform (B2B) to OEMs who then deploy humanoids to healthcare providers and eldercare facilities (B2C).
- Scale network effects via API licensing to 3rd-party developers, insurers, Pharma
- Real-world evidence learnings across fleet, establish “Hive Mind” Data Moat

Business Model: A Multi-Layered Revenue Strategy



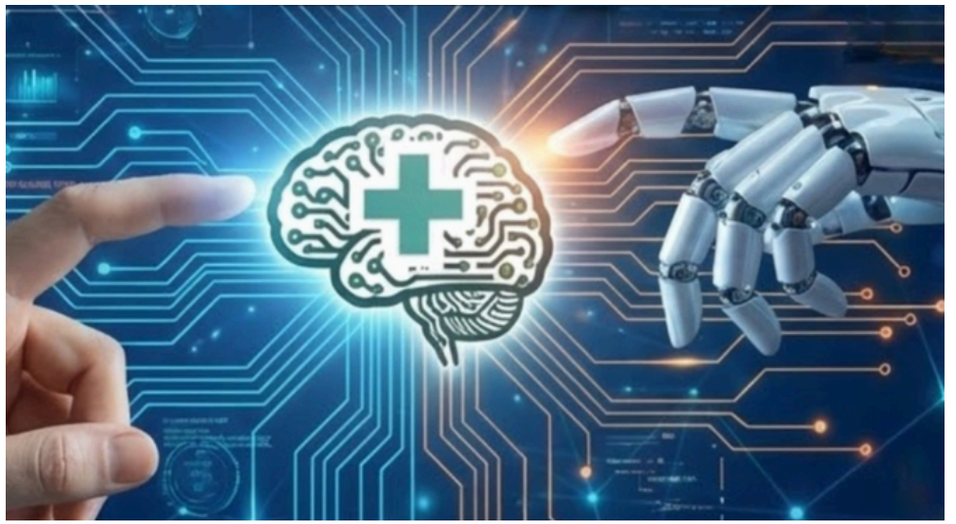
Humanoid Healthcare: Triple Win Value for Ecosystem

The **Orchestrator** that empowers patient independence, saves on hospitalisations, protects Manufacturers & generates recurring revenues



The Industry's Central Nervous System

Asmore OEMs adoptour Safety OS, we become the central nervous system of the healthcare robotics industry



NETWORK EFFECTS

1 **Real-World Evidence Generation**

Each deployment generates data that improves safety protocols for all users. The more robots deployed, the safer and more effective the entire system becomes.

2 **Data Network Effects**

More users lead to better protocols, which attract more users. This creates switching costs and competitive moat that compounds over time.

3 **Infrastructure Layer**

We're not just selling software — we're building the foundational infrastructure layer that the entire healthcare robotics industry will depend on.

$6.0M Seed Round

$3M EU & $3M in US, & dual-track preparation of SaMD/MDR Dossiers

Milestones Achieved

- ✓ Pilot Geriatric Care Homes
- ✓ Expand to cancer patients rehabilitating at home
- ✓ First RWE read
- ✓ Prepare SaMD / MDR Dossiers
- ✓ Partnerships with Robotic Hardware Go2Market

Use of Funds

55% Clinical Pilot & RWE Analysis Development (MVP)

Rapid prototyping, completing MVP SaMD software, pilot deployment with EU hospitals

20% Regulatory Affairs & Quality Systems

FDA / EU MDR certification, ISO 13485, IEC 62304 compliance infrastructure

25% Development, IT, Operations & Legal

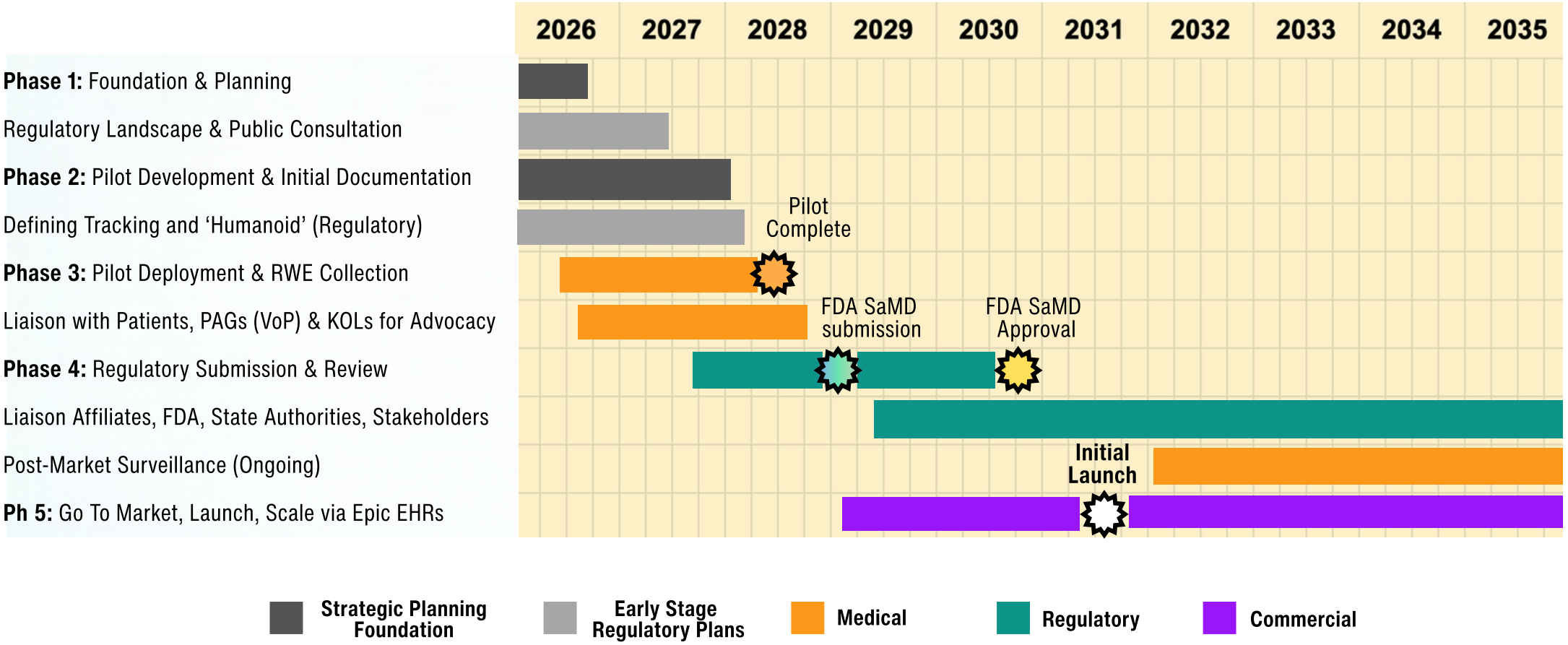
Team expansion, engineering infrastructure, legal entity setup

Appendix: Detailed US Regulatory Pathway

Gantt chart showing a detailed path to Launch in US in 2031. Expect longer in EU

US Humanoid Healthcare Regulatory Pathway to FDA SaMD

Parallel Pilot & Submission Pathways



The Core Argument for US First

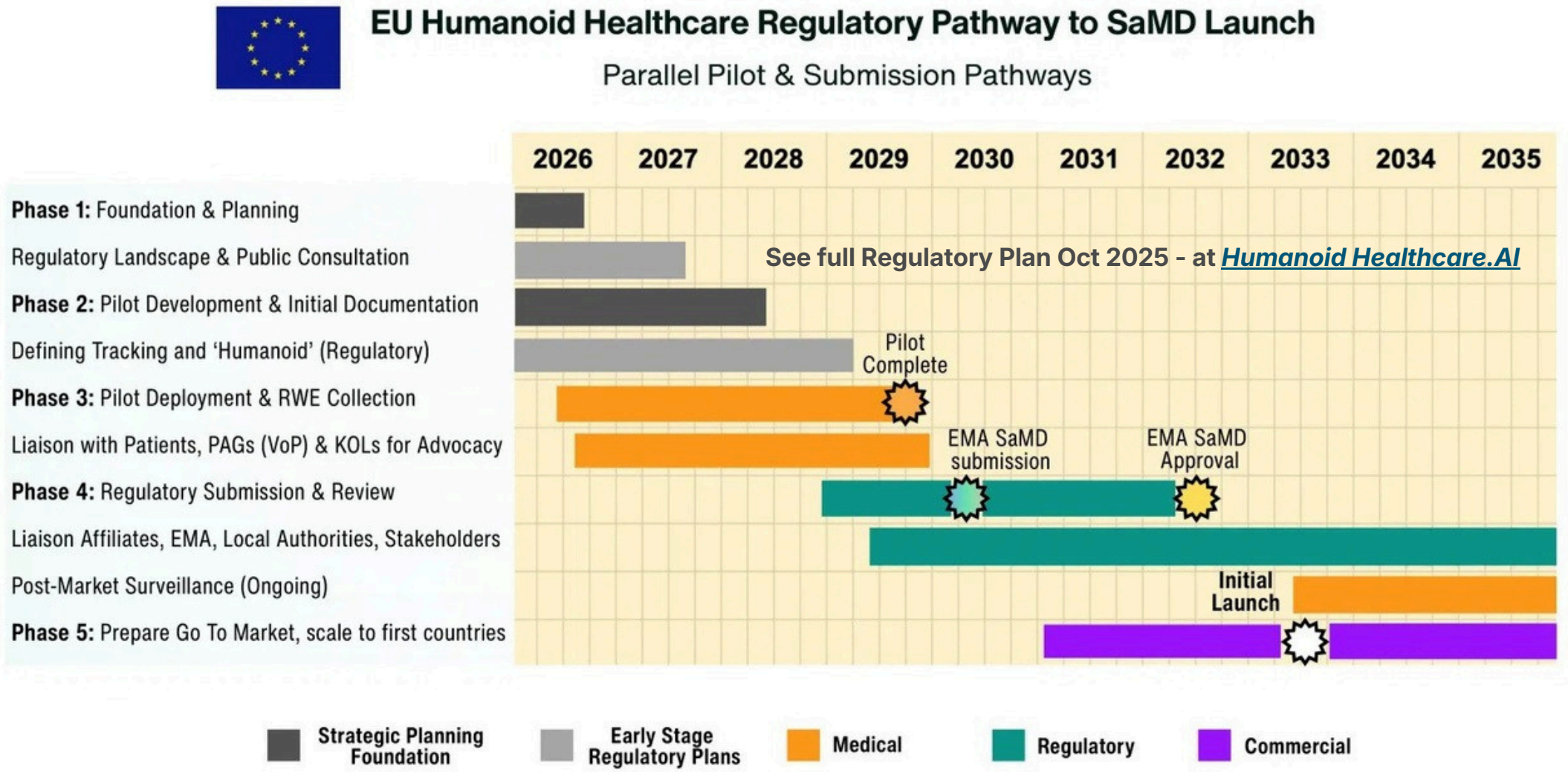
Choosing a US-First Regulatory Strategy is superior to an EU-first approach due to speed, cost, and flexibility.

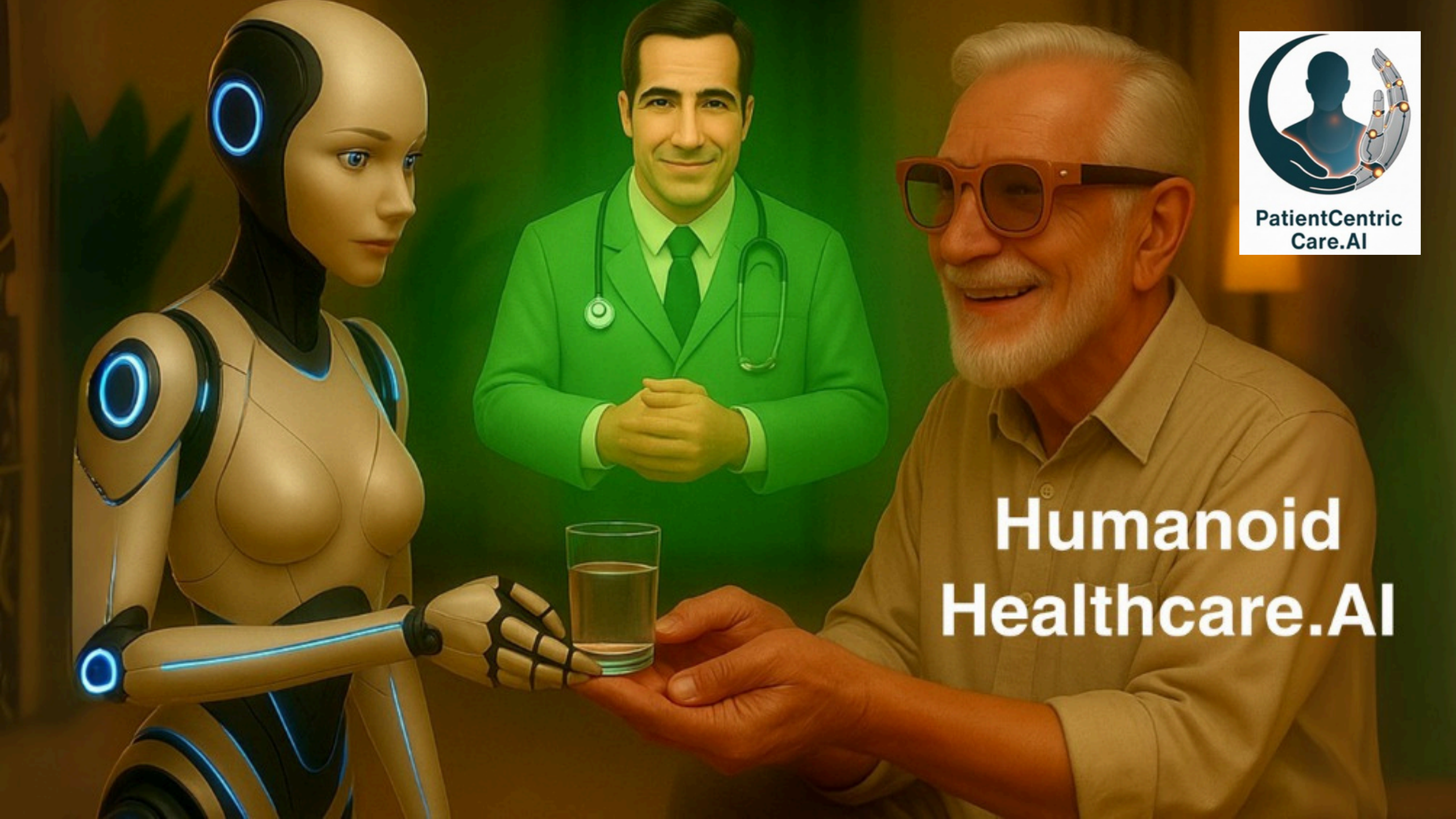
The Pathway: Utilizing FDA Q-Submission and 510(k) processes.
The Timeline: Achieves US Launch in 2031 (2 years ahead of the 2033 EU Launch).
The ROI: This acceleration reduces cash burn and secures First-Mover Advantage in the world's largest healthcare market ($4.5T).

Metric	US FDA Pathway	EU MDR Pathway	US Advantage
Time to Market	2026-2031 (5 years to launch)	2026-2033 (7 years to launch)	2 years faster
US Launch Year	2031	N/A (EU first)	First-mover advantage
EU Launch Year	2033	2033	Parallel expansion
Regulatory Cost	30-40% lower	Higher (Notified Body fees)	Significant savings
AI/ML Flexibility	Adaptive algorithms supported (PCCP)	More prescriptive	Innovation friendly
Market Access	$4.5T US healthcare market	Fragmented (27 member states)	Largest market first
Regulatory Engagement	Q-Submission (early FDA feedback)	Limited pre-submission options	Risk mitigation

Appendix: EU Regulatory Pathway

Gantt chart showing a detailed path to Launch in US in 2031. Expect shorter in US

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